PE Screening Test for Human Salivary a-Amylase

A. SCOPE

A.1 This Rapid Stain Identification (RSID™ - Saliva) test is an immunochromatographic one-step test for the detection of human salivary α-amylase. In this test procedure, a specimen is added to the sample well, "S" and allowed to be absorbed by the test strip. If human salivary α-amylase is present in the specimen, it will react with the mobile monoclonal anti-human antibody that is conjugated to colloidal gold and form a mobile complex. This mobile complex migrates through the absorbent device towards the test area "T". In the test area "T" another monoclonal anti-human antibody is immobilized. This immobilized antibody captures the above complex so that an antibody-antigen-antibody sandwich is formed. A pink colored band in the test area "T" indicates a positive result. The RSID™ - Saliva test can detect as little as 1 µL of human saliva. The antiimumoglobulin on the control line captures any unbound antibodies flowing past the test area "T", producing a pink line at the control area "C" demonstrating the test strip worked correctly.

B. QUALITY CONTROL

B.1 Each new lot number must be tested with a known positive and negative control before use.

B.2 Results must be documented in the Laboratory Asset Management System (LAM).

B.3 A positive control must be tested each day of use prior to or in conjunction with the testing any unknown or suspected saliva samples.

B.4 Results of the day of use quality control testing must be documented in the case notes and include the lot# and expiration date.

B.5 If the quality control measures do not produce the expected result, the test will not be used on evidentiary samples and troubleshooting will be performed. New solutions or materials may be required.

C. SAFETY

C.1 Treat all biological samples as potentially infectious. Gloves, a face mask, eye protection (e.g. safety glasses or a face shield) and a lab coat must be worn.

C.2 The appropriate manufacturer's product insert must be read prior to performing this procedure for the first time.

C.3 Distinguish all waste as general, biohazard or sharps and discard appropriately.

D. REAGENTS, STANDARDS, AND CONTROLS

D.1 A known saliva sample is used to test the cards.

D.2 RSID™ - Saliva test cards

D.2.1 This kit may be used until depleted; however, the kit must be discarded on its expiration date.

D.3 Store the test packets at room temperature.

D.4 The extraction and running buffers will be stored in the refrigerator.

E. EQUIPMENT

E.1 Tubes

E.2 Pipettes

E.3 Vortex

E.4 Timer

F. PROCEDURES

F.1 Allow the sample, extraction buffer, and running buffer to warm to room temperature.

F.2 Place a small cutting (~1-2 mm^2) of the stain into 200 µL of the extraction buffer, vortex, and allow it to extract at room temperature for 1-2 hours.

F.3 Remove the RSID™ - Saliva test card from the sealed pouch.

F.4 Label the device.

F.5 Add 40 µL of the extraction buffer containing the stain into 60 µL of the running buffer.

F.6 Add all 100 µL of the extraction buffer and running buffer mixture into the sample well "S".

F.7 Read result in 10 minutes. A positive result can be observed earlier then 10 minutes, but negative results must be given the entire 10 minutes.

G. INTERPRETATION GUIDELINES

G.1 If there are two pink lines, one each in the test area "T" and in the control area "C," the test result is positive. The test will detect as little as 1 µL of human saliva.

G.2 If there is only one pink line (in the control area "C"), the test result is negative. This may indicate that either human saliva is not present or there is less then 1 µL of human saliva.

G.3 If there is no pink line visible in the control area "C", the test is inconclusive. Repeat the test and reexamine the test procedure carefully.

G.4 The RSID™ - Saliva test may react with breast milk, menstrual blood, and fecal material. In circumstances where citrus fruit may be involved, caution should be exercised during the interpretation of any positive results. The lowering of buffer pH by citrus fruit has been demonstrated to potentially produce false positives.

G.5 The high dose hook effect does not occur with this test.

H. REFERENCES

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